

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 3, 2011 has been entered.

Claims 24-27 and 30-32 have been amended. Claims 21-23, 34-49 are withdrawn. Claims 24-27, and 30-33 are under examination in this Office action.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Rejection of Claims 24-27 and 30-32 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an immunogenic composition comprising the recombinant adenovirus RAdEs, does not reasonably provide enablement for the recombinant adenovirus RAdEs vaccine, **is withdrawn** in view of Applicant's amendment.

Rejection of Claims 24, 26 and 30 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement **is withdrawn** in view of Applicant's amendment.

Rejection of Claims 25, 27 and 31-32 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement **is maintained**.

Applicant states that the declaration stating the deposit of ECACC Accession Number 0412101 was made at an acceptable depository and the criteria for the biological deposit requirement have been met.

In response the Examiner notes that Applicant's declaration and arguments are not sufficient to overcome the present rejection for the following reasons:

1) In the Remarks on June 3, 2011 on page 7 Applicant states that "the declaration stating the deposit of ECACC Accession Number 0412101 was made at an acceptable depository". However the present claims recite a different deposit number 04121701 and not 0412101.

2) Applicant failed to amend the specification to add the information about the biological deposit. There is no mention about the ECACC Accession Number 0412101 or 04121701 in Applicant's specification or the claims as originally filed. The identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.803 - 37 CFR 1.809 for additional explanation of these requirements.

3) It is noted that the biological deposit was filed after the effective filing date of the present Application. The effective filing date of the present Application is January 4, 2004 and the biological deposit was made on December 17, 2004. In this situation Applicant must comply with the following:

*37 CFR 1.804 Time of making an original deposit*

(b) When the original deposit is made after the effective filing date of an application for patent, the applicant must promptly submit a statement from a person in a position to corroborate the fact, stating that the biological material which is deposited is a biological material specifically identified in the application as filed.

[MPEP 2406.01] The requirement for a specific identification is consistent with the description requirement of the first paragraph of 35 U.S.C. 112 and provides an antecedent basis for the biological material which either has been or will be deposited before the patent is granted.

[MPEP 2406.02] Deposit After Filing Date - Corroboration

When the original deposit is made after the effective filing date of an application for patent, an applicant is required to promptly submit a statement from a person in a position to corroborate that the biological material which is deposited is a biological material specifically identified in the application (the filing date of which is relied upon) as filed. The nature of this corroboration will depend on the circumstances in the particular application under consideration, including the length of time between the application filing date and the date of deposit.

Thus because Applicant failed to comply with the requirements listed above the rejection is maintained.

***New Rejection and Objection***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claims 24-27, and 30-32 are rejected under 35 U.S.C. 112, second paragraph,** as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant's claims recite (RADEs) and (ECACC Accession Number 04121701) in parenthesis. The meaning of the parenthesis in the claims is not clear and it is not clear whether

the phases recited in the parenthesis are necessary limitations of the present invention. Correction and/or clarification is required.

***Claim Objections***

Claims 24 and 33 are objected to because of the following informalities: It appears that the claims recite "1" the SEQ ID NO: 1 as a subscript. Appropriate correction is required.

***Conclusion***

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Zachariah Lucas can be reached on 571-272-0905. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Agnieszka Boesen/  
Examiner, Art Unit 1648